



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-D-0316]

Small Entity Compliance Guide: Bottled Water: Quality Standard: Establishing an Allowable Level for di(2-ethylhexyl)phthalate; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Bottled Water: Quality Standard: Establishing an Allowable Level for di(2-ethylhexyl)phthalate--Small Entity Compliance Guide.” The small entity compliance guide (SECG) is being issued for a final rule published in the Federal Register of October 19, 2011, and is intended to set forth in plain language the requirements of the regulation and to help small businesses understand the regulation.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the SECG to the Division of Plant and Dairy Food Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition, (HFS-317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send one self-addressed adhesive label to assist that office in processing your request. See the SUPPLEMENTARY INFORMATION section for electronic access to the SECG.

Submit electronic comments on the SECG to <http://www.regulations.gov>. Submit written comments on the SECG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:**I. Background**

In the Federal Register of October 19, 2011 (76 FR 64810), FDA issued a final rule that amended its bottled water standard of quality regulations by establishing an allowable level for di(2-ethylhexyl)phthalate (DEHP). This final rule is effective April 16, 2012.

FDA examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule will not have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Public Law 104-121), FDA is making available this SECG stating in plain language the requirements of the regulation.

FDA is issuing this SECG consistent with FDA's good guidance practices regulation (21 CFR 10.115(c)(2)). This SECG represents the Agency's current thinking on di(2-ethylhexyl)phthalate in bottled water. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this SECG. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the SECG at either <http://www.fda.gov/RegulatoryInformation/Guidances/default.htm> or <http://www.regulations.gov>. Always access an FDA guidance document by using FDA's Web site listed previously to find the most current version of the guidance.

Dated: April 26, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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